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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/672,049      | 09/29/2000  | Johannes Platzek     | SCH-1722            | 2997             |

23599 7590 05/07/2003

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.  
2200 CLARENDON BLVD.  
SUITE 1400  
ARLINGTON, VA 22201

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| EXAMINER |
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WELLS, LAUREN Q

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1617

DATE MAILED: 05/07/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n No.

09/672,049

Applicant(s)

PLATZEK ET AL.

Examiner

Lauren Q Wells

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 March 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 6-15, 17-22 and 26-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 16, 23-25, 39 and 40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-40 are pending. Claims 6-15, 17-22, 26-38 are withdrawn from consideration, as they are directed toward non-elected subject matter. The Amendment filed 3/4/03, Paper No. 15, amended claims 1-3, 5 and 16 and added claims 39-40.

Following Applicant's response to the Office Action of 8/26/02, Paper No. 13, are five pages which describe an Example 1, an Example 2, an Example 3, and an Example 4. What is the purpose of these papers?

Applicant is again reminded that acknowledgement is made for foreign priority based on an application filed in Germany on 9/29/99. It is noted, however, that applicant has not filed a certified copy of the German application as required by 35 USC 119(b).

#### ***Response to Applicant's Arguments/Amendment***

The Applicant's arguments filed 3/4/03 (Paper No. 15) to the rejection of claims 1-5, 16, 23-25 made by the Examiner under 35 USC 103 have been fully considered and deemed not persuasive.

The Applicant's amendment filed 3/4/03, Paper No. 15, is sufficient to overcome the 35 USC 112 rejections in the previous Office Action.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 39 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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(i) Claim 39 is vague and indefinite, as it is confusing. Applicant recites "the ratio (singular).of paramagnetic. . .to the diamagnetic perfluoroalkyl compound". However, Application recites two ratios (plural). Is Applicant actually claiming two ratios or is Applicant claiming a ratio range of 40:60-60:40?

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 16, 23-25 and 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Platzek et al. (WO 97/26017) in view of Milius et al. (New J. Chem 1992).

The instant invention is directed toward galenical formulations comprising paramagnetic perfluoroalkyl and diamagnetic perfluoroalkyl compounds.

197 28954 Platzek et al. teach perfluoroalkyl-substituted, paramagnetic metal complexes for use in NMR, X-ray diagnostics, radiodiagnostics, and radiotherapeutic agents. Specifically disclosed is Complex I, Rf-L-M, wherein Rf is C8F17, L is a direct bond, and M is that of general formula XI of the instant invention when Z1=Gd, q=1, p=0. The reference lacks diamagnetic perfluoroalkyl-containing substances. See pg. 2-pg. 3; pg. 162-180.

Milius et al. teach perfluoroalkylated anionic sugar phosphodiesteres that are utilized in numerous biomedical applications, such as in vivo oxygen carriers, contrast agents, and drug delivery systems. Disclosed are compounds of formula Rf-L1-B2, wherein Rf is C8F17, L1 is CH2CH2, and B2 is a disaccharide. See entire disclosure.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the perfluoroalkyl-substituted, paramagnetic metal complexes of Platzek et al. and the perfluoroalkyl anionic sugars of Milius et al. because a) both compounds are disclosed as contrast agents and it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 USPQ 1069 (CCPA 1980); b) the compounds of Milius et al. are effective emulsifiers of fluorocarbons and the compounds of Platzek et al. contains fluorocarbons.

Regarding the ratios and percent weights, it is respectfully pointed out that it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

#### ***Response to Arguments***

Applicant argues, "it would not be obvious to combine the two types of perfluoroalkyl compounds, one being paramagnetic and the other diamagnetic. The former type of compound acts as a contrast agent because its paramagnetism has an effect on, e.g., in the typical MRI procedure, the hydrogen atoms in water. In such images, it is not the paramagnetic agent which is seen; rather, it is the hydrogen atoms in water and tissue which are depicted. . .the diamagnetic compound itself is imaged in a negative way, i.e., one observes a void on an image due to the presence of the diamagnetic compound". This argument is not persuasive. The Examiner respectfully points out, as stated in the previous Office Action, both compounds are disclosed for use as contrast agents and it is obvious to combine individual composition taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 USPQ 1069 (CCPA 1980). Additionally, it would have been obvious to one of

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ordinary skill in the art at the time the invention was made to combine the two compounds because of the expectation of achieving enhanced imaging. While the Examiner agrees that the two agents act through different means to produce images, it is respectfully pointed out that the end result of both is to produce an image. Thus, while they may act in different ways to produce an image, both compounds have the same utility. . .to produce a contrast image.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-5:30), with alternate Mondays off.

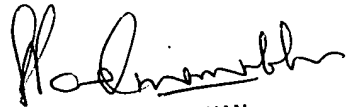
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone numbers for

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the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw  
April 28, 2003

  
SREENI PADMANABHAN  
PRIMARY EXAMINER

5/4/03